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DECLARATION

I, Natsuko Tosa, hereby declare:

that I am a translator belonging to KYOWEY INT'L of 2-32-1301 Tamatsukuri-Motomachi, Tennoji-ku, Osaka, 543-0014 Japan;

that I am well acquainted with both the Japanese and English languages;

that the attached document is a true translation of Japanese Patent Application No. 2002-193845 to the best of my knowledge and belief.

I also declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statements is directed.

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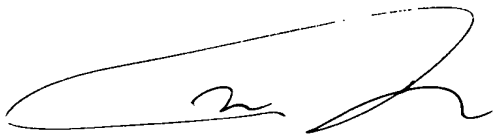

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【Title of the Invention】 LANCING APPARATUS

【Claims】

【Claim 1】

A lancing apparatus comprising:

a moving mechanism for holding a lancing member and advancing the lancing member in a first direction; and

a holding portion for arranging and holding an auxiliary part at a position spaced from a path of the advancing movement of the lancing member in a second direction crossing the first direction;

wherein at least one of the auxiliary part and the lancing member is movable in the second direction.

【Claim 2】

The lancing apparatus according to claim 1, wherein the holding portion is capable of moving the auxiliary part in the second direction.

【Claim 3】

The lancing apparatus according to claim 2, wherein the moving mechanism detachably holds the lancing member; and wherein a cap for covering a needle of the lancing member is attached to the lancing member, the holding portion being capable of moving the auxiliary part toward the advancing movement path of the lancing member when the cap is separated from the lancing member with the lancing member held by the moving mechanism.

【Claim 4】

The lancing apparatus according to claim 3, wherein the holding portion includes a first wall, a second wall located closer to the advancing movement path of the lancing member than the first wall, a space defined between the first and the second walls into which the auxiliary part can be partially inserted movably in the second direction, and a resilient member for pressing a portion of the auxiliary part toward the second wall when the auxiliary part is partially inserted into the space.

【Claim 5】

The lancing apparatus according to any one of claims 1-4, wherein, when the lancing member advances, the lancing member engages the auxiliary part so that the advancing movement of the lancing member is controlled.

【Claim 6】

The lancing apparatus according to any one of claims 1-5, wherein the holding portion allows movement of the auxiliary part in a direction opposite from the first direction when the auxiliary part receives a force in said direction.

【Claim 7】

The lancing apparatus according to any one of claims 1-6, further comprising a measurement probe,
wherein the measurement probe is brought into contact with an electrode provided at the auxiliary part as a result of movement of the auxiliary part toward the advancing movement path of the lancing member.

【Claim 8】

A lancing apparatus comprising for performing lancing operation using a lancing unit provided with a lancing member with a needle, a cap connected to the lancing member for covering the needle, a auxiliary part, and a supporter for supporting the components of the lancing unit, the lancing apparatus comprising:

a moving mechanism for detachably holding a lancing member and advancing the lancing member in a first direction; and

a holding portion for detachably holding the auxiliary part and arranging the auxiliary part at a position spaced from a path of the advancing movement of the lancing member;

wherein the holding portion is capable of moving the auxiliary part toward the advancing movement path of the lancing member when the cap and the supporter are separated from the lancing member and the auxiliary part, with the lancing member and the auxiliary part held by the moving mechanism and the holding portion.

【Detailed Description of the Invention】

【0001】

【Field of the Invention】

The present invention relates to a lancing apparatus used to extract body fluid such as blood and to analyze such body fluid.

【0002】

【Prior Art】

For diabetes treatment, management of the blood glucose level by a patient himself or herself is important for maintaining the blood glucose level in a normal range. Particularly, for a patient of insulin-dependent diabetes, regular measurement of the blood glucose level is essential to maintain the blood glucose level in a normal range. However, it is troublesome to often go to a medical institution for measuring the blood glucose level. Conventionally, therefore, apparatuses which enable the extraction and analysis of blood without going to a medical institution have been proposed. For example, JP-A 2001-74731 discloses a lancing unit as shown in Fig 18. Fig. 19 shows a lancing unit used in the lancing apparatus.

【0003】

First, description is made as to the lancing unit 9 shown in Fig. 19. The lancing unit 9 includes a lancet 90 as a lancing member, and a first housing 91A accommodating part of the lancet. The first housing 91A is fixedly fitted to a second housing 91B. As shown in Fig. 18, the second housing 91B is provided with a test strip 92 and a blood introduction portion 95. The first housing 91A has an opening 91a which is closed by a cover 93 so that a sterilized needle 90a of the lancet 90 can be kept hygienically clean. The first and the second housings

91A and 91B are wrapped by a wrapping member 94 in the form of a bag or case.

【0004】

As shown in Fig. 18, the lancing apparatus 8 includes a housing case 80 accommodating a lancet holder 81. The first and the second housings 91A and 91B of the lancing unit 9 can be mounted to the housing case 80. Therefore, the lancet 90 and the test piece 92 can be mounted simultaneously. When the lancet 90 pushes a lancet holder 81 to the right in the figure, a spring 82 is compressed to bring the lancing apparatus 8 into a locked state. Thereafter, when an operation switch 83 is operated with the lancing apparatus 8 pressed against the skin of a human body, the lancet holder 81 and the lancet 90 advance to the left in the figure due to the resilient force of the spring 82, whereby the needle 90a of the lancet 90 lances the skin of the human body. The blood bleeding from the skin as a result of the lancing is introduced from the blood introduction portion 95 to the test sheet 92 through the blood introducing portion 95. The blood can be analyzed by optically detecting the color reaction, using a light-emitting element 84a and a light-receiving element 84b.

【0005】

With such structure, lancing of the human skin and analysis of blood sampled by the lancing are successively performed. Thus, the above-described lancing apparatus

8 is convenient for a user in comparison with a conventional lancing apparatus capable of lancing operation only.

【0006】

【Problems to be Solved】

In the lancing apparatus 8, it is desirable that the blood introduction portion 95 is located as close to the lancing position as possible. This is because, as the blood introduction portion 95 is farther from the lancing position, the blood is less likely to come into contact with the blood introduction portion 95 properly. Even when the blood comes into contact with the blood introduction portion 95, the amount of blood reaching the test piece 92 is small, whereby accurate analysis result may not be obtained.

【0007】

In the lancing apparatus 8, since the first case 91B is fixed to the housing 80 while the lancet 90 moves reciprocally along a predetermined path, the distance s5 between the path and the blood introduction portion 95 is always constant. In the prior art arrangement, therefore, to locate the blood introduction portion 95 close to the lancing position, the blood introduction portion 95 need be provided close to the needle 90a of the lancet 90 in the state of the lancing unit 9 shown in Fig. 19 (though this figure does not show the blood introduction portion). However, in actually designing

and manufacturing the lancing unit 9, various points need be taken into consideration such as reduction in size of the entire unit and the airtightness of the first case 91A, so that it is sometimes difficult to locate the blood introduction portion 95 sufficiently close to the needle 90a of the lancet 90. Therefore, in the prior art arrangement, it is difficult to locate the blood introduction portion 95 sufficiently close to the lancing position, so that the amount of blood introduced to the test piece 92 is sometimes insufficient.

【0008】

In mounting an auxiliary part with a test piece and a lancet to a lancing apparatus, differently from the conventional art in which the auxiliary part and the lancet are mounted together, the auxiliary part and the lancet may be mounted separately. In this case, in order to locate the auxiliary part close to the lancing position of the lancet, it is required to locate a needle of the lancet close to the auxiliary part in the lancing apparatus. However, it also is difficult to locate the lancet needle sufficiently close to the auxiliary part. Especially, when it is required to reliably prevent the lancet needle from lancing a hand of the user in mounting operation, it is difficult to locate the lancet needle sufficiently close to the auxiliary part. Further, when the lancet needle is located too close to the auxiliary

part, the mounting operation may be very troublesome for the user.

【0009】

The present invention has been proposed under the above-described circumstances. It is therefore an object of the present invention to provide a lancing apparatus in which the auxiliary part is easily located close to the lancing position, and thus the amount of sample supplied to the auxiliary part is prevented from being insufficient.

【0010】

【Means for Solving the Problems】

To solve the above problems, the present invention provides the following technical means.

【0011】

According to a first aspect of the present invention, there is provided a lancing apparatus comprising: a moving mechanism for holding a lancing member and advancing the lancing member in a first direction; and a holding portion for arranging and holding an auxiliary part at a position spaced from a path of the advancing movement of the lancing member in a second direction crossing the first direction. At least one of the auxiliary part and the lancing member is movable in the second direction.

【0012】

With such structure, by moving at least one of the auxiliary part and the lancing member in the second direction, a distance between the auxiliary part and the lancing member in the second direction is changed. Specifically, by moving the auxiliary part toward the path of the advancing movement of the lancing member, in lancing operation, the auxiliary part is located closed to the lancing portion, so that the amount of body fluid such as blood supplied to the auxiliary part is prevented from being insufficient. On the other hand, in mounting the lancing member and the auxiliary part to the lancing apparatus, for example, by separating the auxiliary part and the lancing member away from each other, the mounting operation is facilitated. If the auxiliary part and the lancing member are formed as a unit, its manufacture is facilitated.

【0013】

Preferably, the holding portion is capable of moving the auxiliary part in the second direction. With such structure, there is not need to make the lancing member to be movable in the second direction. Since the lancing member moves in the first direction for lancing, it may be complicated when making the lancing member to be movable in the second direction. In this view, the above structure is largely less complicated.

【0014】

Preferably, the moving mechanism detachably holds the lancing member. A cap for covering a needle of the lancing member is attached to the lancing member, the holding portion being capable of moving the auxiliary part toward the advancing movement path of the lancing member when the cap is separated from the lancing member with the lancing member held by the moving mechanism. With such structure, until the lancing member is mounted to the moving mechanism and the cap is removed, the lancing member and the auxiliary part are located away from each other, thereby facilitating the mounting operation. If the lancing member and the auxiliary part are formed as a unit, since the distance between the lancing member and the auxiliary part are allowed to be relatively large, its design and manufacture is facilitated. Further, since the lancing member is moved close to the lancing position by removing the cap from the lancing member, the user is not required to perform any operation, which is convenient.

【0015】

Preferably, the holding portion includes a first wall, a second wall located closer to the advancing movement path of the lancing member than the first wall, a space defined between the first and the second walls into which the auxiliary part can be partially inserted movably in the second direction, and a resilient member for pressing a portion of the auxiliary part toward the second wall

when the auxiliary part is partially inserted into the space. With such structure, by using a auxiliary part which is positioned by the cap of the lancing member, when the cap is removed from the lancing member and the auxiliary part is released, the auxiliary part is moved toward the advancing movement path of the lancing member using the pressing force of the resilient member. Further, the auxiliary part may be supported by pressing a part of the auxiliary part toward the second wall using the pressing force of the resilient member. In this way, the structure of the holding portion is simplified, while moving and holding of the auxiliary part is reliably performed.

【0016】

Preferably, when the lancing member advances, the lancing member engages the auxiliary part so that the advancing movement of the lancing member is controlled. With such structure, the lancing member is prevented from sticking deep into the human skin more than necessary, by efficiently using the auxiliary part.

【0017】

Preferably, the holding portion allows movement of the auxiliary part in a direction opposite from the first direction when the auxiliary part receives a force in said direction. With such structure, in lancing operation, with a part of the lancing apparatus brought into contact with the human skin as a lancing target, when the skin

bulges, the auxiliary part is accordingly moved in the direction of bulging of the skin. In this way, the auxiliary part is prevented from unnecessarily pressing the skin, whereby the skin bulges properly.

【0018】

Preferably, the lancing apparatus further comprising a measurement probe. The measurement probe is brought into contact with an electrode provided at the auxiliary part as a result of movement of the auxiliary part toward the advancing movement path of the lancing member. With such structure, when the auxiliary part is not moved toward the advancing movement path of the lancing member, the measurement probe and the electrode of the auxiliary part is prevented from electrical connection, thereby preventing unnecessary power consumption.

【0019】

According to a second aspect of the present invention, there is provided a lancing apparatus comprising for performing lancing operation using a lancing unit provided with a lancing member with a needle, a cap connected to the lancing member for covering the needle, a auxiliary part, and a supporter for supporting the components of the lancing unit, the lancing apparatus comprising: a moving mechanism for detachably holding a lancing member and advancing the lancing member in a first direction; and a holding portion for detachably holding the auxiliary part and arranging the auxiliary part at

a position spaced from a path of the advancing movement of the lancing member. The holding portion is capable of moving the auxiliary part toward the advancing movement path of the lancing member when the cap and the supporter are separated from the lancing member and the auxiliary part, with the lancing member and the auxiliary part held by the moving mechanism and the holding portion.

【0020】

With such structure, after the lancing member of the lancing unit and the auxiliary part are held by the moving mechanism and the holding portion and the cap is removed from the lancing member, the lancing member is located close to the auxiliary part. Thus, when advancing the lancing member for lancing operation, the auxiliary part is reliably located closed to the lancing portion, thereby properly sampling body fluid such as blood. Further, in the lancing unit, since the auxiliary part may be formed away from the lancing member, there is no need to design the auxiliary part to be positioned close to the lancing member, thereby facilitating the design and manufacture.

【0021】

Other features and advantages of the present invention will be apparent from the following description of the embodiments.

【0022】

【Mode for Carrying out the Invention】

Preferred embodiments of the present invention will be described below in detail with reference to the accompanying drawings.

【0023】

Figs. 1-6 show an example of lancing unit used in a lancing apparatus according to the present invention. To facilitate understanding of the lancing apparatus according to the present invention, descriptions are made first with respect to the lancing unit.

【0024】

As better shown in Figs. 1 and 2, the lancing unit U includes a case 1, a lancet 2, a cap 29 and a sensor holder 3.

【0025】

The case 1 is a supporter made of synthetic resin, and includes a generally cylindrical tubular portion 10 having an end (upper end) formed with an opening 12, and a bottom portion 11 connected to another end (lower end) of the tubular portion 10. The tubular portion 10 has an inner circumferential surface formed with a projection 13, which stops the rotation of the case 1 in fitting the case 1 around a part of a lancing apparatus A, which will be described later. A film 14 as a lid for closing the opening 12 is bonded to the upper surface of the case 1, whereby the case 1 is hermetically closed. As the film 14, use may be made of one made of an aluminum foil or

one provided by laminating a resin film onto an aluminum foil.

【0026】

As better shown in Figs. 3, the lancet 2 includes a body 20 made of synthetic resin and a metal needle 21 held by the body 20 with its tip end protruding out of the body 20. The body 20 is so configured as to be properly mounted to a lancet holder 5 of the lancing apparatus A, which will be described later, and formed with a plurality of ribs 22 extending in the same direction as the needle 21 and with a recess 23.

【0027】

The cap 29 is formed integrally on the body 20 by resin molding for covering the needle 21 and extends on the front end side (lower end side) of the body 20 in the same direction as the needle 21. The boundary portion 28 between the cap 29 and the body 20 is constricted to be smaller in diameter than other portions, for facilitating divide of the two parts. The cap 29 has a lower end formed with a hole 29a. As shown in Fig. 6, the hole 29a can be fitted to a projection 15 projecting from the bottom portion 11 of the case 1. By the fitting, the cap 29 is held in the case 1 in a standing posture. In the present invention, conversely to the above structure, the bottom portion 11 of the case 1 may be formed with a recess, whereas the bottom of the cap 29 may be formed with a projection to be fitted in the recess. The cap 29 is

bonded to the case 1 with an adhesive. Instead of using an adhesive, the bonding may be performed by ultrasonic welding or thermal fusing. This holds true for the bonding between other portions of the lancing unit. The needle 21 of the lancet 2 is subjected to sterilization by e.g. γ-ray irradiation before it is incorporated into the case 1. Preferably, in the case 1 is further disposed a desiccant (not shown) for keeping the quality of a sensor S, which will be described later. The cap 29, the body 20 and the case 1 may be integrally formed.

【0028】

The sensor holder 3 is an example of analyzing member of the present invention. As better shown in Fig. 4, the sensor holder 3, which is made of synthetic resin, includes a side wall 31 having an arcuate cross section and a horizontal wall 32 connected to the side wall 31. The horizontal wall 32 has a bottom surface which is inclined, for example, and to which the sensor S is attached.

【0029】

The sensor S is in the form of a chip and has a structure as shown in Figs. 5A and 5B, for example. The sensor S includes a substrate 390 on which are provided a reagent 39a containing enzyme which undergoes certain reaction (e.g. oxidation reaction) with glucose in blood, and a pair of electrodes 39b for electrically detecting the degree of the reaction. On the substrate 390 are also

provided a pair of spacers 391 spaced from each other, and a cover 392 for covering the spacers 391, all of which serve to define a capillary 393. The substrate 390, each of the spacers 391 and the cover 392 are continuously formed with a recess 394 which serves as a blood introduction port. When blood is applied to the recess 394, the blood travels through the capillary 393 by capillary action and is guided to the reagent 39a.

【0030】

As shown in Fig. 4, the horizontal wall 32 of the sensor holder 3 is formed with a pair of through-holes 32a and a pair of holding walls 32b. The paired through-holes 32a are utilized for inserting a pair of measurement probes 62 of the lancing apparatus A, which will be described later, to bring the measurement probes 62 into contact with the paired electrodes 39b of the sensor S. The paired holding walls 32b can be fitted around a lower portion 29b of the cap 29 so as to clip the lower portion from opposite sides. For example, the lower portion 29b of the cap 29 is columnar, whereas the paired holding walls 32b are curved into a generally arcuate shape corresponding to the circumferential surface of the lower portion. As shown in Figs. 1 and 2, by fitting the paired holding walls 32b around the lower portion of the cap 29, the sensor holder 3 is attached to the case 1 via the cap 29. However, the sensor holder 3 is slidable upward for detachment from the cap 29.

【0031】

In the lancing unit U, the case 1 is hermetically closed by the film 14. Therefore, the reagent 39a of the sensor S is not exposed to e.g. moisture, whereby the quality deterioration in a short period of time is prevented. Since the needle 21 of the lancet 2 is covered by the cap 29 and the cap 29 is integrally formed on the body 20 of the lancet 2, the needle is also hermetically sealed. Therefore, the sterilized state of the needle can be properly maintained from the state before the lancet 2 is incorporated into the case 1.

【0032】

The lancing unit U is manufactured by mounting the lancet 2 provided with the cap 29 into the case 1, mounting the sensor holder 3 to the cap 29, and then sealing the opening 12 of the case 1 by the film 14. Therefore, the manufacture is easy. Specifically, the manufacture of the lancing unit U1 is easy particularly because the lancet 2 can be mounted just by fitting the hole 29a of the cap 29 to the projection 15 of the case 1 and the sensor holder 3 can be mounted just by fitting the paired holding walls 32b around the cap 29, thereby reducing the product cost.

【0033】

Figs. 7-16 show an example of lancing apparatus and the structural parts.

【0034】

As shown in Fig. 7, the lancing apparatus A of this embodiment includes a housing 4, a lancet holder 5 arranged in the housing 4, a latch member 59 and other members to be described below.

【0035】

The housing 4 is provided by connecting three sleeves 40a-40c constituting a front end portion, an intermediate portion, and a rear end portion in series and is fixed to an outer case 70. The sleeve 40a has a front end (lower end) which comes into contact with the skin of a human body in performing lancing and which has an opening 41. As shown in Fig. 11, the sleeve 40a has a configuration and a size which make it possible to fit the case 1 of the lancing unit U to the sleeve by sliding. The sleeve 40a has an outer surface formed with a groove 42 for receiving the projection 13 of the case 1. The groove 42 extends longitudinally of the sleeve 40a to prevent the rotation of the case 1 in fitting the case 1 around the sleeve 40a. In the lancing apparatus A, the lancet 2 and the sensor holder 3 of the lancing unit U are mounted to the lancing apparatus A by sliding and fitting the case 1 around the sleeve 40a, whereby the lancet 2 and the sensor holder 3 are precisely guided to predetermined positions in the lancing apparatus A, which will be described later.

【0036】

As better shown in Fig. 8, in the sleeve 40a, a holding portion 6 is provided. The holding portion 6 serves to hold the sensor holder 3 of the lancing unit U and includes an attachment 60, fixed to the inner surface of the sleeve 40a, which is made of synthetic resin and includes a first and a second walls 60b and 60c defining a space 60a. As shown in Figs. 12 and 13, the space 60a is a portion for inserting the side wall 31 of the sensor holder 3 of the lancing unit U from below. The holding portion 6 is provided with a spring 61, and when the side wall 31 enters the space 60a, the spring 61 exerts a resilient force F for pushing the side wall 31 toward the second wall 60c, or toward the central portion of the sleeve 40a, for holding the sensor holder 3. Of course, for reliable holding of the sensor holder 3, an engaging member may be provided between the sensor holder 3 and the holding portion 6.

【0037】

As better shown in Fig. 13, the space 60a has a width s1 which is larger than the thickness t1 of the side wall 31 of the sensor holder 3. Therefore, when the side wall 31 of the sensor holder 3 attached to the case 1 is inserted into the space 60a, a gap 60a' is defined between the side wall 31 and the second wall 60c. Therefore, as shown in Fig. 14, when the sensor holder 3 and the cap 29 are separated from each other, the resilient force F of the spring 61 presses the side wall 31 of the sensor holder

3 against a side surface of the second wall 60c. In the state shown by the figure, the sensor holder 3 is movable in the vertical direction indicated by an arrow N6, along the side surface of the second wall 60c.

【0038】

Referring to Figs. 7 and 8, the paired measurement probes 62 are held in the second wall 60c of the holding portion 6. The paired measurement probes 62 for coming into contact with the paired electrodes 39b of the sensor S extend axially of the housing 4. Each of the measurement probes 62 has an expandable and contractible front end 62a which is extended downward by a resilient force of an appropriate spring (not shown) when the sensor holder 3 is not mounted to the lancing apparatus A. As shown in Figs. 12-14, when the sensor holder 3 is mounted to the holding portion 6, the front end 62a is pushed upward by the sensor S for contraction. Though not shown, the paired measurement probes 62 are electrically connected to a control circuit provided in a proper portion of the outer case 70. The control circuit, which comprises e.g. a CPU and a memory attached thereto, performs computation of the glucose level in blood introduced to the reagent 39a based on the current detected via the paired measurement probes 62.

【0039】

The lancet holder 5 for holding and advancing the lancet 2 is fitted in the sleeve 40b rotatably and slidably in

the axial direction. The lancet holder 5 has a lower end formed with a recess 50. By pushing the body 20 of the lancet 2 into the recess 50, the lancet 2 is removably held by the lancet holder 5. The inside of the recess 50 is formed with a plurality of grooves into which the ribs 22 of the body 20 of the lancet 2 are fitted. With such an arrangement, when the body 20 of the lancet 2 is fitted into the recess 50, the relative rotation between the body 20 and the lancet holder 5 is prevented. As shown in Fig. 9, the lancet holder 5 has a head portion 51 having a circumferential surface formed with a plurality of equiangularly spaced projections 52. The projections 52 are fitted in and guided along a plurality of first guide grooves 43A and second guide grooves 43B formed at an inner wall surface of the sleeve 40b.

【0040】

The first guide grooves 43A serve to rotate the lancet holder 5 when the lancet holder 5 is pushed upward by the lancet 2 of the lancing unit U. The first guide grooves are inclined relative to the axial direction of the sleeve 40b. The second guide grooves 43B serve to guide the straight movement of the lancet 2 and the lancet holder 5 toward the front end of the housing 4, when these parts are caused to advance to lance the skin of a human body with the lancet 2, and extend straight in the axial direction of the sleeve 40b. Figs. 10A-10E are developed plan view of part of the first and the second guide grooves

43A and 43B, which are actually connected to each other. (In these figures, the nearby portions of the first and the second guide grooves 43A and 43B are cross hatched.) When the lancet holder 5 moves in the axial direction of the housing 4, the projections 52 move along the first and the second guide grooves 43A and 43B. The specific operation will be described later in detail.

【0041】

As shown in Figs. 7 and 8, the latch member 59 is connected to an upper portion of the lancet holder 5 and slidably accommodated in the housing 4. The latch member 59 has a lower end into which a bush 58 is non-rotatably fitted. In the bush 58, a plurality of projections 53 projecting from the upper surface of the lancet holder 5 are rotatably inserted. With such an arrangement, the lancet holder 5 is rotatable, whereas the latch member 59 does not rotate in accordance with the rotation of the lancet holder. The upper end of each of the projections 53 engages the upper end of the bush 58 so as not to drop therefrom, whereby the lancet holder 5 and the latch member 59 are connected to each other.

【0042】

The latch member 59 has an upper portion formed with a pair of latch pawls 59a. Each of the latch pawls 59a serves to engage with an edge of a respective one of paired cutouts 44 formed in the sleeve 40c. As will be described later, this engagement occurs when the lancet holder 5

and the latch member 59 are pushed upward by the lancet 2 of the lancing unit U. To the upper portion of the sleeve 40c are mounted a pusher 71 for releasing the latch, and an operation cap 72 connected to the pusher. Between the pusher 71 and an intermediate wall 59b of the latch member 59 is provided a spring 73. The spring 73 may comprise a compression coil spring, for example. The operation cap 72 is slidable relative to the sleeve 40c in the axial direction thereof. Thus, when the operation cap 72 is pushed down while compressing the spring 73, the pusher 71 also moves downward in accordance with the movement of the operation cap to press the latch pawls 59a. As a result, as shown in Fig. 16, the latch pawls 59a are forcibly disengaged from the edges of the cutouts 44, whereby the latch member 59 and the lancet holder 5 advance downward due to the resilient force of the compressed spring 73. In the housing 4 is also provided a return spring 74 for retreating the lancet holder 5 and the latch member 59 after the advancement.

【0043】

Next, the operation and advantages of the lancing apparatus A will be described.

【0044】

First, as shown in Fig. 11, the case 1 of the lancing unit U is fitted around the sleeve 40a of the lancing apparatus A. The film 14 of the case 1 is removed in advance to expose the opening 12. By fitting the case 1 around the

sleeve 40a, the body 20 of the lancet 2 is fitted and retained in the recess 50 of the lancet holder 5, thereby held by the lancet holder 5. As the case 1 is pushed upward in the direction indicated by the arrow N1, the lancet 2 pushes the lancet 5 upwardly. Here, the lancet holder 5 and the body 20 of the lancet 2 rotate in the direction indicated by the arrow N2, whereby the boundary portion 28 between the lancet 2 and the cap 29 is twisted and broken.

【0045】

Specifically, as shown in Fig. 10(a), the projections 52 of the lancet holder 5 are initially located within the second guide grooves 43B, and then move closer to the first guide grooves 43A, as indicated by the arrow N3 in Fig. 10(b). To cause this movement, either the front ends of the ribs 22 of the body 20 of the lancet 2 or the grooves in the recess 50 of the lancet holder 5 are inclined to be helical so that the lancet holder 5 rotates in the direction indicated by the arrow N3 through a slight angle when the body 20 is fitted into the recess 50. Subsequently, when the lancet holder 5 is pushed upward by the lancet 2, the projections 52 move along the first guide grooves 43A, as shown in Figs. 10(c) and 10(d). This operation causes the lancet holder 5 to rotate, whereby the body 20 of the lancet 2 also rotates. On the other hand, the cap 29 of the lancing unit U does not rotate because it is fixed to the case 1. Therefore, the

boundary portion 28 between the body 20 of the lancet 2 and the cap 29 is twisted, whereby the boundary portion 28 is broken.

【0046】

As shown in Fig. 12, when the case 1 is pushed upward by an appropriate amount, the latch member 59 also moves upward, whereby each of the latch pawls 59a engages with an edge of a respective one of the cutouts 44. Thus, the latch member 59 is latched. As shown in Fig. 13, when the case 1 is pushed upward, the side wall 31 of the sensor holder 3 enters the space 60a of the holding portion 6, and receives the resilient force F of the spring 61. When the sensor holder 3 is supported by the cap 29, the sensor holder keeps its posture while resisting the resilient force F, whereby the gap 60a' is kept between the second wall 60c and the side wall 31. The front end 62a of each measurement probe 62 is pushed upward by the sensor S and exerts a resistive force to the pushing, thereby being brought into contact with the relevant electrode 39b. Thus, the measurement probe 62 is reliably electrically connected to the relevant electrode 39b.

【0047】

After the pushing up of the case 1 is completed in the above-described manner, the case 1 is pulled down for detachment from the sleeve 40a, as shown in Fig. 14. Since the boundary portion 28 between the body 20 of the lancet 2 and the cap 29 has been twisted and broken as

noted above, the lancet 2 and the cap 29 readily separate from each other. By this separation, the lancet 2 is duly mounted to the lancet holder 5 with the needle 21 exposed, while the cap 29 is kept in the case 1. The sensor holder 3 separated from the cap 29 is secured to the holding portion 6. As noted above, in the lancing unit U and the lancing apparatus A, the mounting of the lancet 2 to the lancet holder 5, the latching of the latch member 59, the separation of the cap 29 from the lancet 2, and the mounting of the sensor holder 3 to the holding portion 6 can be performed just by fitting the case 1 around the sleeve 40a by sliding the case by an appropriate amount and then pulling out the case, which is convenient. Since the cap 29 is kept fixed to the case 1, these parts can be easily disposed of.

【0048】

When sensor holder 3 and the cap 29 are separated each other by pulling out the case 1 from the sleeve 40a, the side wall 31 of the sensor holder 3 is pressed against the second wall 60c by the resilient force F of the spring 61. As a result, the sensor holder 3 moves toward the center of the sleeve 40a (in the direction indicated by the arrow N4 in Fig. 14) by the amount corresponding to the dimension of the gap 60a' shown in Fig. 13. By moving the sensor holder 3 in this way, the sensor S comes close to the lancing position of the lancet 2, which provides the following advantages.

【0049】

As shown in Fig. 15, after the lancet 2 and the sensor holder 3 are mounted to the lancing apparatus A by the above process, the front end of the sleeve 40a of the lancing apparatus A is brought into contact with the skin 99 of a human body as the object to be lanced. When the front end of the sleeve 40a is brought into contact with the skin 99, a part of the skin 99 in contact with the opening of the sleeve 40a may bulge. Preferably, a pump or a pump mechanism is provided in the lancing apparatus A to generate a negative pressure in the sleeve 40a in lancing the skin. With such an arrangement, the negative pressure promotes the bleeding from the skin 99, so that the lancing amount of the needle 21 of the lancet 2 can be reduced, which is advantageous for reducing the damage to the skin 99. Since the sensor holder is made movable upward as described above, when the skin 99 bulges, the sensor holder 3 is lifted as indicated by the arrow N7. Therefore, the sensor holder 3 does not hinder the bulging of the skin 99.

【0050】

Subsequently, the operation cap 72 is pushed to advance the pusher 71. As a result, as shown in Fig. 16, each of the latch pawls 59a is disengaged from the edge of the relevant cutout 44, whereby the latch member 59 and the lancet holder 5 move downward by the resilient force of the spring 73 to cause the needle 21 of the lancet 2 to

lance the skin 99. At this time, the body 20 of the lancet 2 partially engages the horizontal wall 32 of the lancet holder 3, whereby the needle 21 is prevented from sticking deep into the skin 99 more than necessary. As shown in Fig. 10(e), when the lancet holder 5 moves downward, the projections 52 move along the second guide grooves 43B, whereby the lancet holder 5 can move straight. As a result of the straight movement, the projections 52 can be located at a position which is similar to the initial position shown in Fig. 10(a), which enables the repeating of the above operation.

【0051】

After the needle 21 lances the skin 99, the latch member 59 and the lancet holder 5 immediately retreat by a predetermined amount due to the resilient force of the return spring 74 to pull out the needle 21 from the skin 99. The blood extracted from the skin 99 is applied to the sensor S and guided to the reagent 39a of the sensor S. As described with reference to Fig. 14, the sensor holder 3 has approached the center of the sleeve 40a, i.e. located closer to the lancing position, so that the blood can be reliably applied to a predetermined portion of the sensor S.

【0052】

As means for positioning the sensor holder 3 close to the center of the sleeve 40a, it may be considered to mount the sensor holder 3 close to the center of the case 1 from

the first in the state of the lancing unit U shown in Figs. 1 and 2. However, since the sensor holder 3 is supported by the cap 29 in the lancing unit U, the wall thickness of the cap 29 need be reduced for positioning the sensor holder 3 close to the center of the case 1. When the wall thickness of the cap 29 is excessively reduced, the mechanical strength of the cap may be deteriorated. In such a case, the cap 29 may not reliably support the sensor holder 3. In this embodiment, however, such a problem can be avoided, because the sensor holder 3 moves closer to the center of the sleeve 40a when it is mounted to the lancing apparatus A.

【0053】

After the lancing operation is performed, the control circuit incorporated in the lancing apparatus A computes the glucose level in blood. In the lancing apparatus A, the computed value may be displayed at a display (not shown) such as a liquid crystal display, for example. The lancet 2 and the sensor holder 3 after use are detached from the lancing apparatus A and disposed of. Preferably, such detachment is performed by using a tool or a member which is designed to enter the sleeve 40a to engage and hold the lancet 2 and the sensor holder 3. In such a case, the user need not directly touch the lancet 2 and the sensor holder 3 after use.

【0054】

Fig. 17 is a sectional view showing a principal portion of another example of lancing apparatus according to the present invention. In the figure, the elements which are identical or similar to those of the foregoing embodiment are designated by the same reference signs as those used for the foregoing embodiment.

【0055】

The holding portion 6A of the lancing apparatus shown in the figure includes a supporting element 69 for removably supporting the sensor holder 3. The supporting element is reciprocally movable, by a driving force of a driver 68, in a direction (indicated by the arrow N5) crossing the direction of the reciprocal movement of the lancet 2. As the driver 68, use may be made of various kinds of devices such as a small-sized linear motor or an actuator utilizing an electromagnetic force which can cause the reciprocal movement.

【0056】

With such an arrangement, the distance between the supporting element 69 and the lancet holder 5 can be kept relatively large before the lancet 2 and the sensor holder 3 are mounted to the lancet holder 5 and the supporting element 69, respectively. Such a large distance facilitates the mounting of the lancet 2 and the sensor holder 3 when these members are mounted one by one. Further, the possibility that the user's hand touches the needle 21 of the lancet 2 by mistake in mounting the sensor

holder 3 can be reduced. After the lancet 2 and the sensor holder 3 are mounted, the supporting element 69 is moved at an appropriate timing to move the sensor holder 3 close to the advancing movement path of the lancet 2, i.e. close to the lancing position. Thus, the advantages intended by the present invention are duly obtained. In this way, in the present invention, driving means other than a spring may be utilized for moving the auxiliary part (sensor holder 3 in this embodiment) in a direction crossing the advancing direction of the lancet.

【0057】

The present invention is not limited to the foregoing embodiments. Specific structure of each part of the lancing apparatus according to the present invention may be modified in various ways.

【0058】

In the lancing apparatus according to the present invention, it suffices if the moving mechanism serves to hold and advance the lancing member in a predetermined direction. Instead of the holder, the moving mechanism may be provided with a clamping mechanism for holding the lancing member, for example. Further, instead of a coil spring, other biasing means may be utilized in the moving mechanism for advancing the lancing member.

【0059】

The lancing apparatus of the present invention are not limited to those used for measuring the glucose level in

blood, but may be structured for use in other kinds of measurement and analysis by changing the structure of the auxiliary part mounted on the lancing apparatus. The auxiliary part in the present invention may not comprise a sensor holder to which a sensor provided with a reagent is mounted. For example, the auxiliary part may comprise a sensor itself provided with e.g. a reagent on a base board, or the test strip itself described as the conventional art.. The lancing member according to the present invention may be designed differently from the above-described lancet.

【Brief Description of the Drawings】

【Fig. 1】 is a perspective view, partially cut away, showing an example of lancing unit according to the present invention.

【Fig. 2】 is a side sectional view of Fig. 1.

【Fig. 3】 (a) is a perspective view showing a lancet with a cap, and (b) is a sectional view thereof.

【Fig. 4】 is a perspective view showing a sensor holder.

【Fig. 5】 (a) is a perspective view showing a sensor, (b) is an exploded perspective view of the sensor.

【Fig. 6】 is an exploded view, partially in section, of the lancing unit shown in Fig. 1.

【Fig. 7】 is a sectional view showing an example of lancing apparatus according to the present invention.

【Fig. 8】 is a sectional view of the principal portion of Fig. 7.

【Fig. 9】 illustrates the lancet holder and the intermediate sleeve for guiding the holder.

【Fig. 10】 (a)-(e) illustrate the guiding of the projections of the lancet holder.

【Fig. 11】 is a sectional view of a principal portion in the process of mounting the lancet and the sensor holder of the lancing unit.

【Fig. 12】 is a sectional view showing the process of mounting the lancet and the sensor holder of the lancing unit.

【Fig. 13】 is a sectional view showing a principal portion of Fig. 12.

【Fig. 14】 is a sectional view showing a principal portion after the lancet and the sensor holder of the lancing unit are mounted to the lancing apparatus.

【Fig. 15】 is a sectional view showing an example of use of the lancing apparatus.

【Fig. 16】 is a sectional view showing an example of use of the lancing apparatus.

【Fig. 17】 is a sectional view showing another example of the present invention.

【Fig. 18】 is a sectional view showing a prior art lancing apparatus.

【Fig. 19】 is a sectional view showing a prior art lancing unit used in the lancing apparatus of Fig. 18.

【Legend】

U lancing unit

A	lancing apparatus
S	sensor
1	case (supporting member)
2	lancet (lancing member)
3	sensor holder
4	housing
5	lancet holder
6	holding portion
10	cylindrical portion
12	opening (of the case)
14	film (lid)
20	body (of the lancet)
21	needle (of the lancet)
28	boundary portion
29	cap (needle cover)

【Identification of the Document】 ABSTRACT

【Abstract】

【Object】

To provide a lancing apparatus in which the auxiliary part is easily located close to the lancing position, and thus the amount of sample supplied to the auxiliary part is prevented from being insufficient.

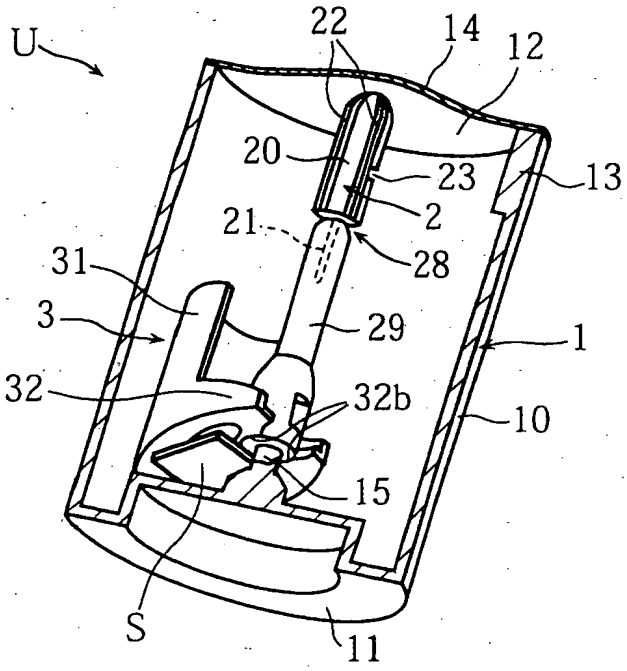
【Means】

A lancing apparatus A includes a moving mechanism for holding a lancing member 2 and advancing the lancing member 2 in a first direction; and a holding portion 6 for arranging and holding an auxiliary part 3 at a position spaced from a path of the advancing movement of the lancing member 2 in a second direction crossing the first direction. At least one of the auxiliary part 3 and the lancing member 2 is movable in the second direction.

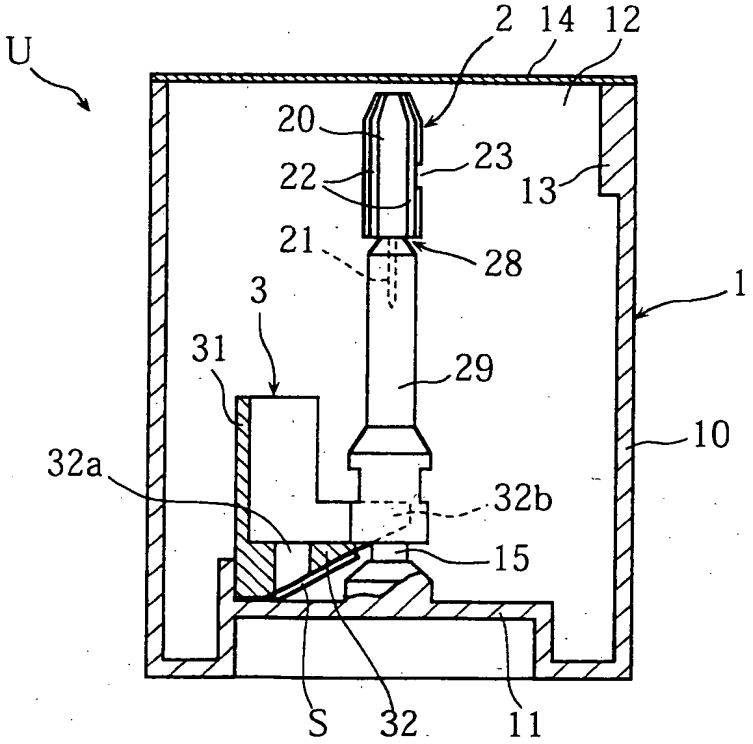
【Selected Figure】 Fig. 13

【Identification of Document】 Drawings

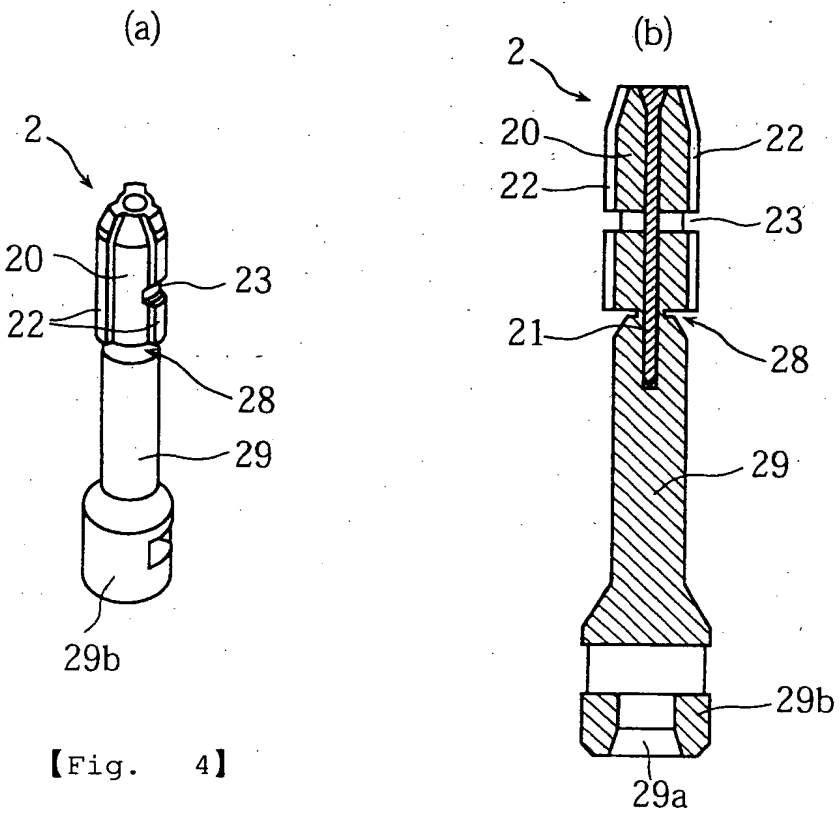
【Fig. 1】



【Fig. 2】



【Fig. 3】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2
20
22
23
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(b)
2
20
22
22
23
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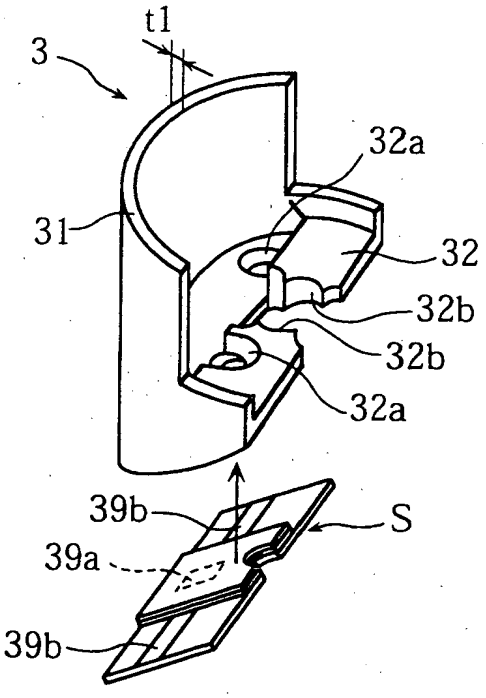
29b
29a

【Fig. 4】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39b
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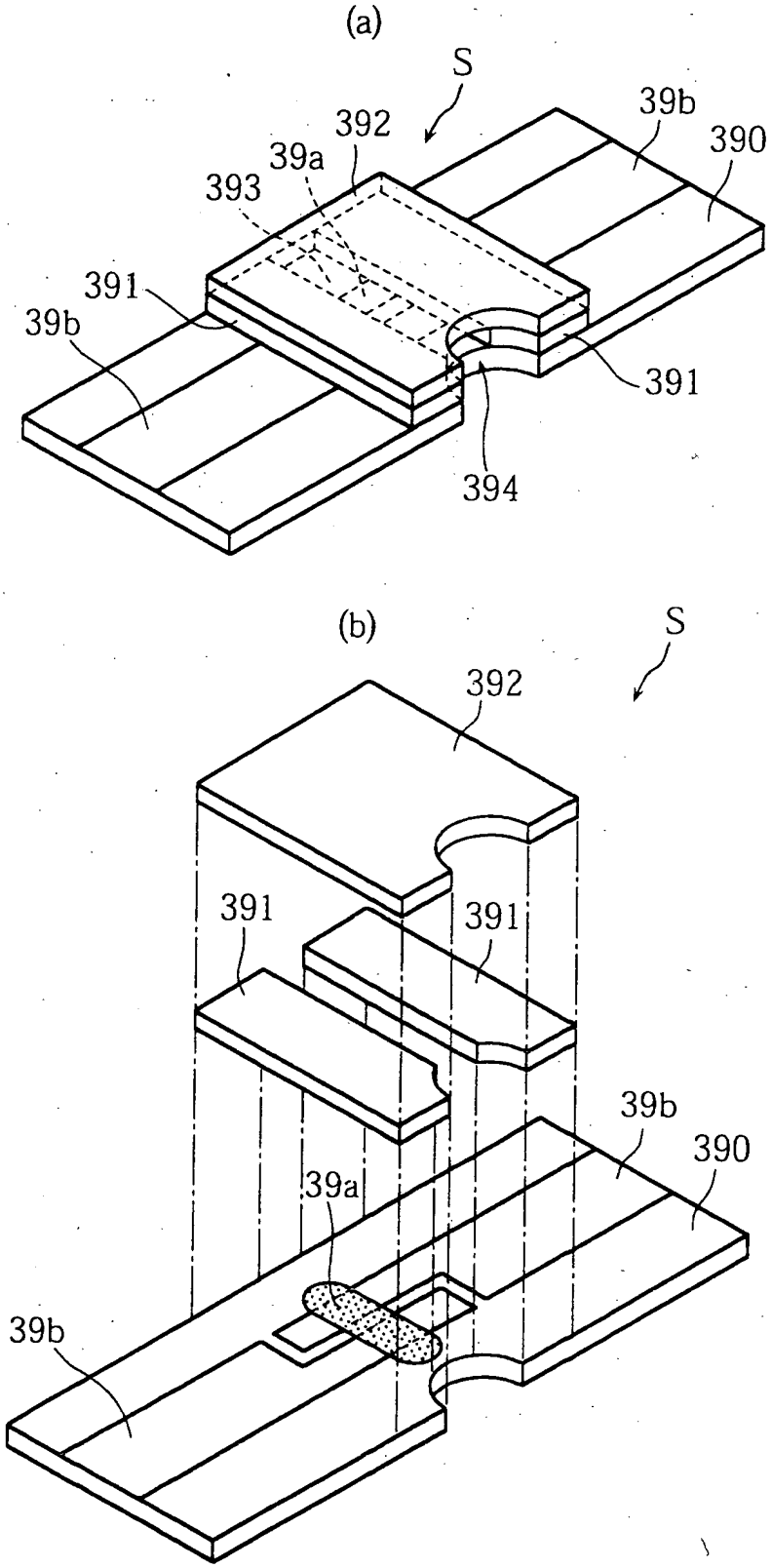
39a
39b

【Fig. 5】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39b
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(b)
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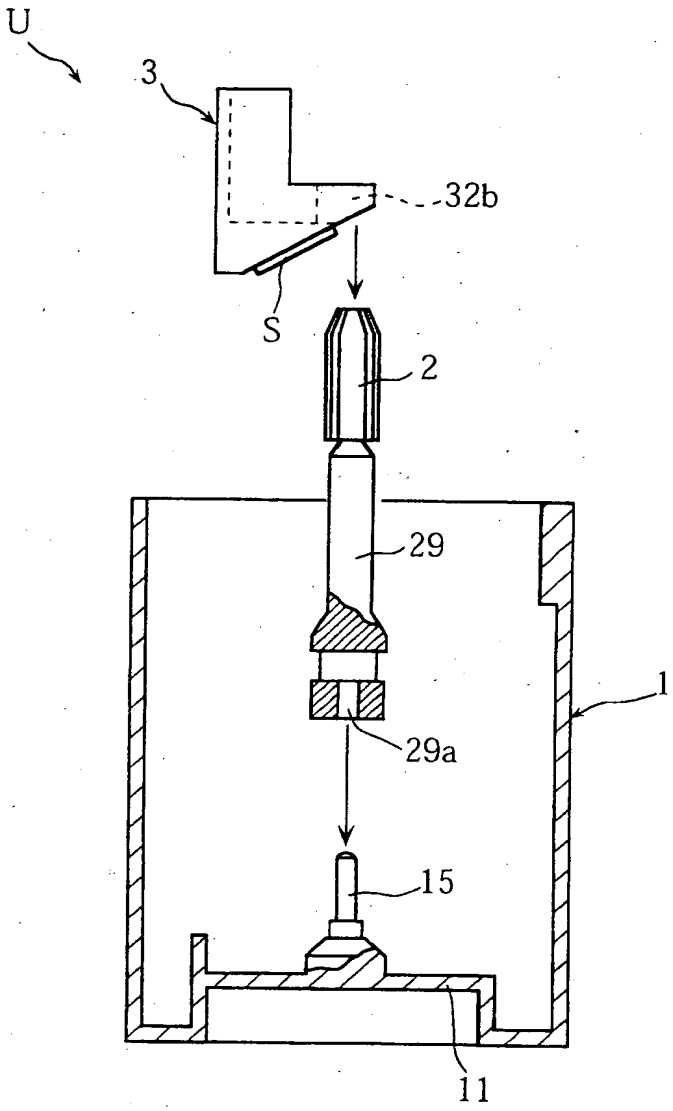
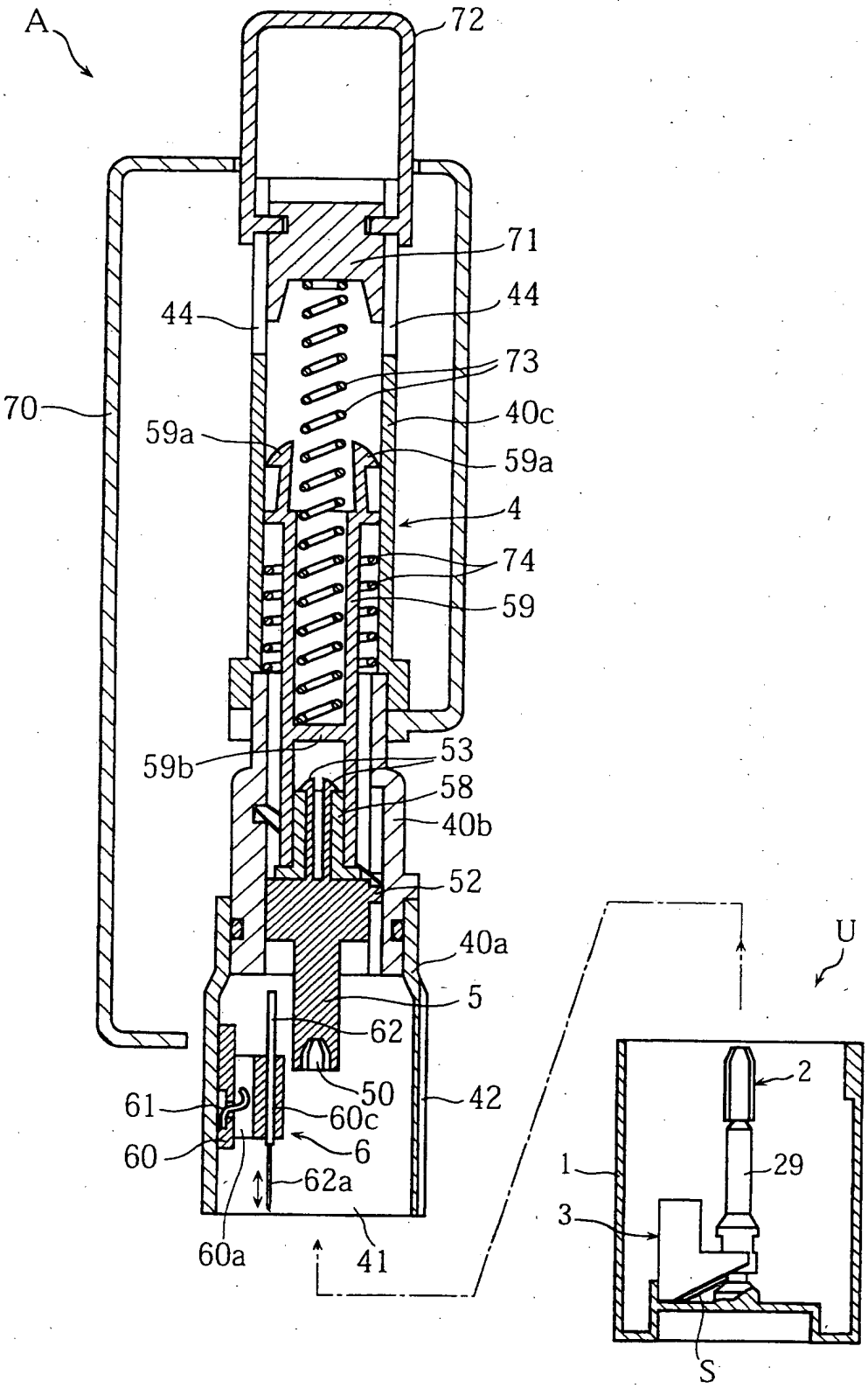
39a
39b

【Fig. 6】



【Fig. 7】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40a
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41
U
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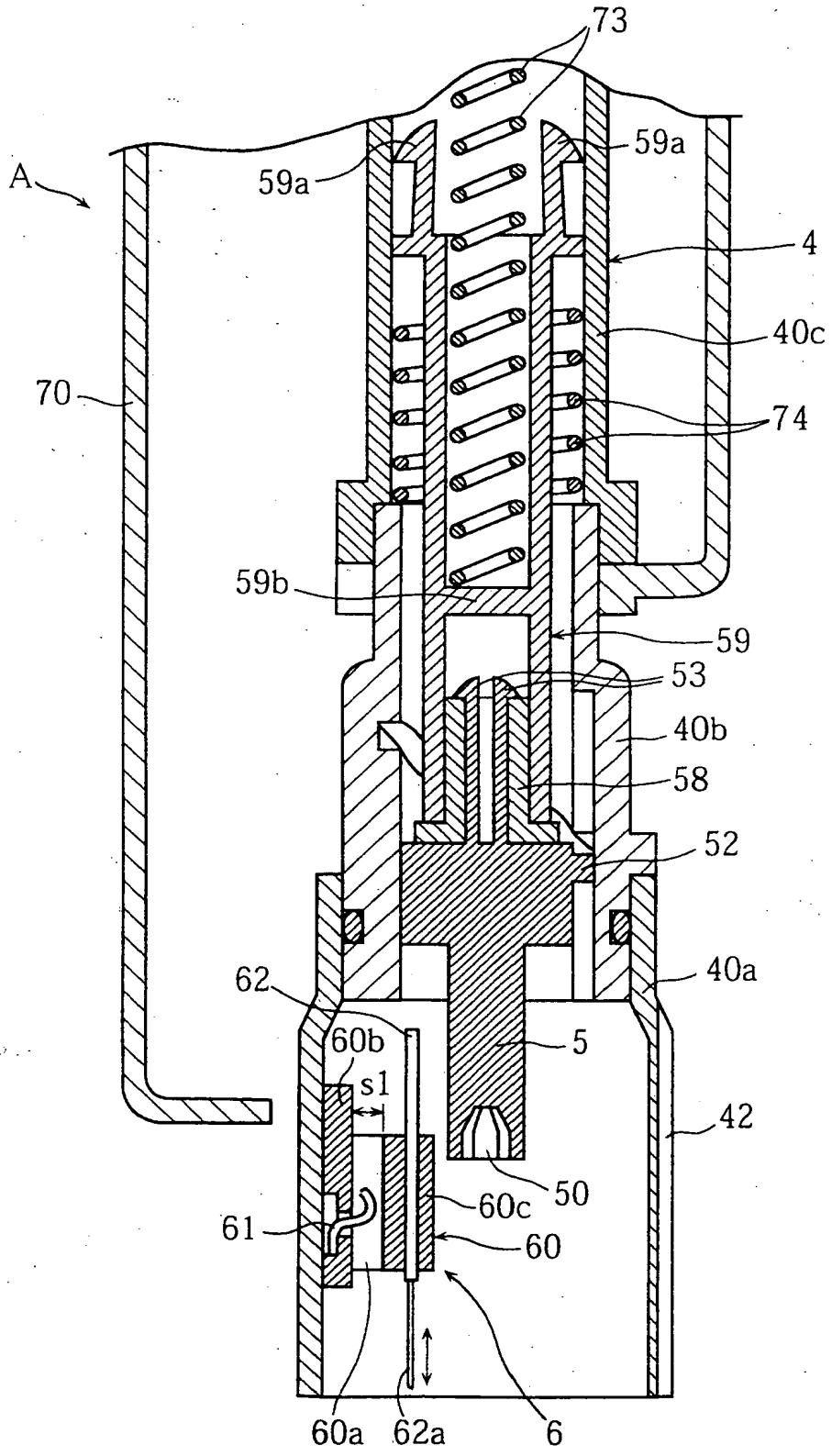
3
S

【Fig. 8】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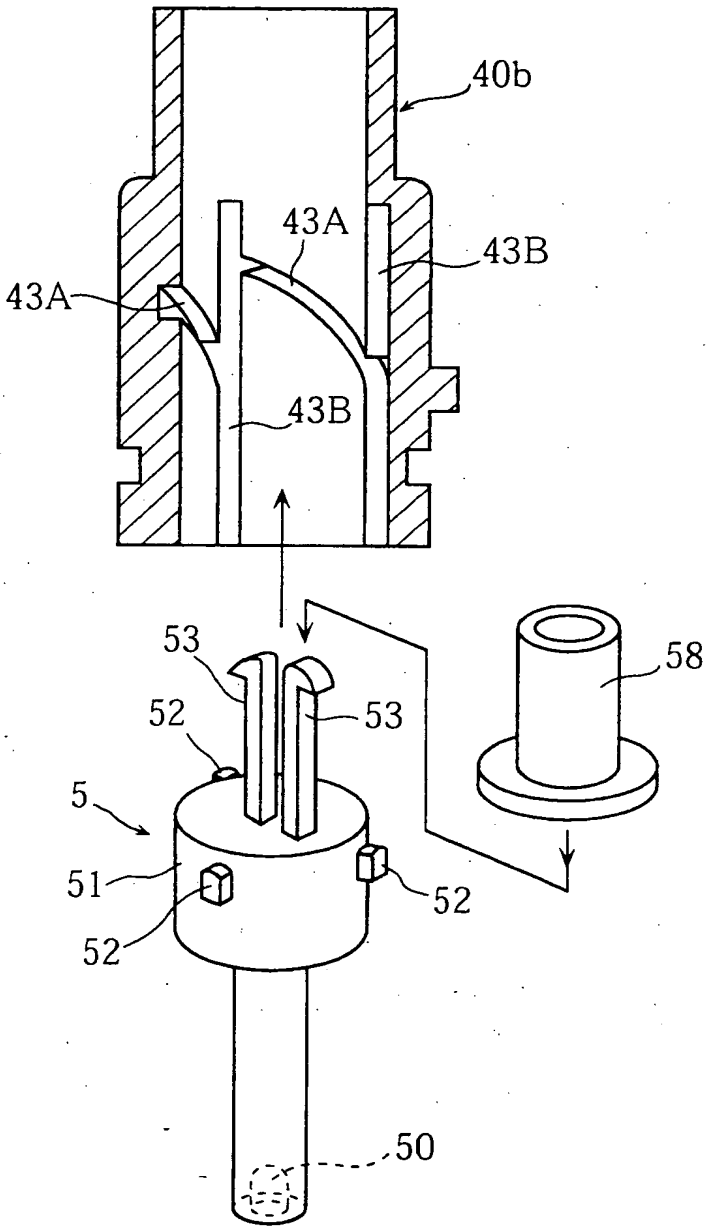
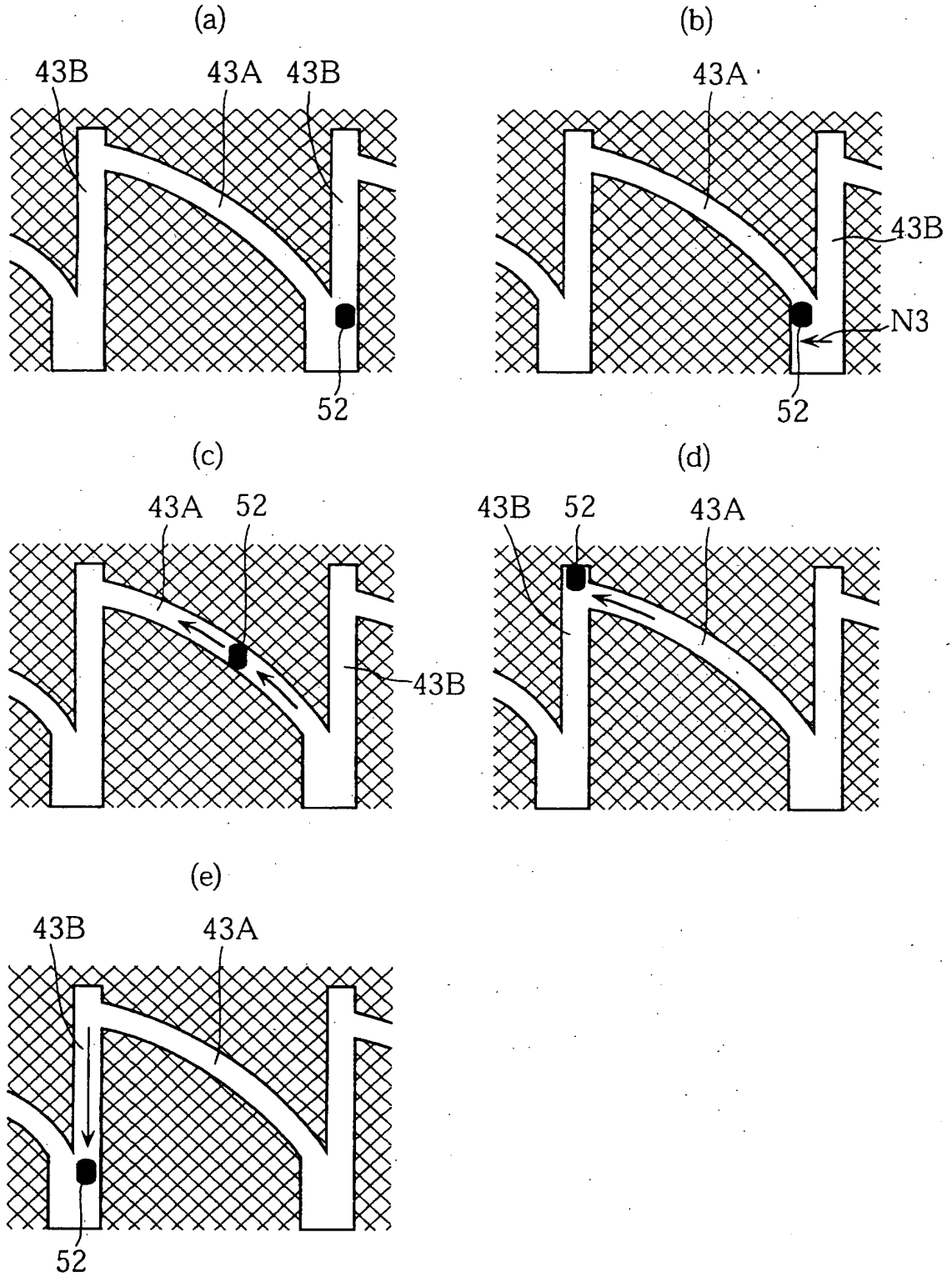
【Fig. 9】



【Fig. 10】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(b)
43A
43B
N3
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(c)
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43B
(d)
43B
52
43A
(e)
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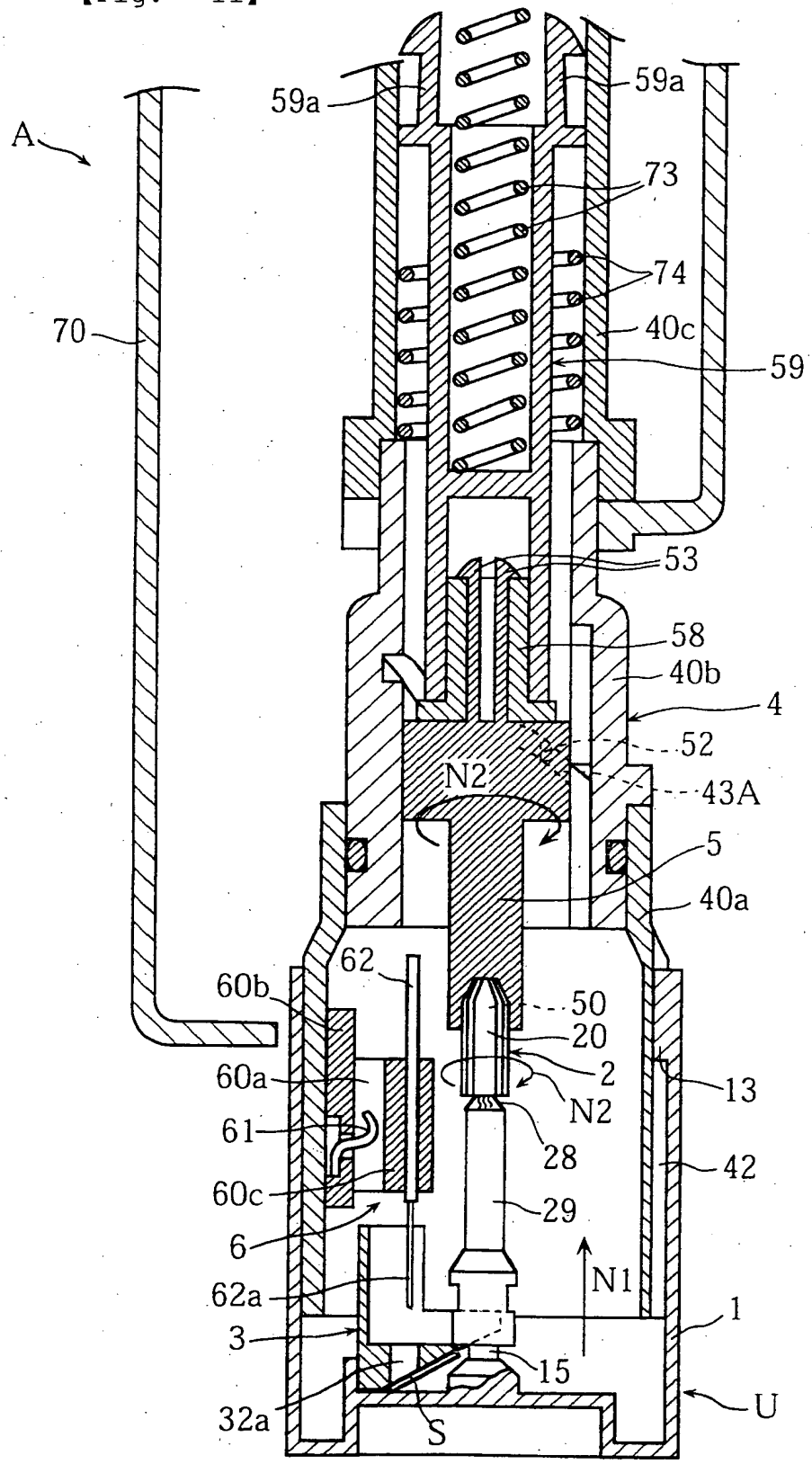
43A
52

【Fig. 11】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50
20
60a
2
13
N2
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6
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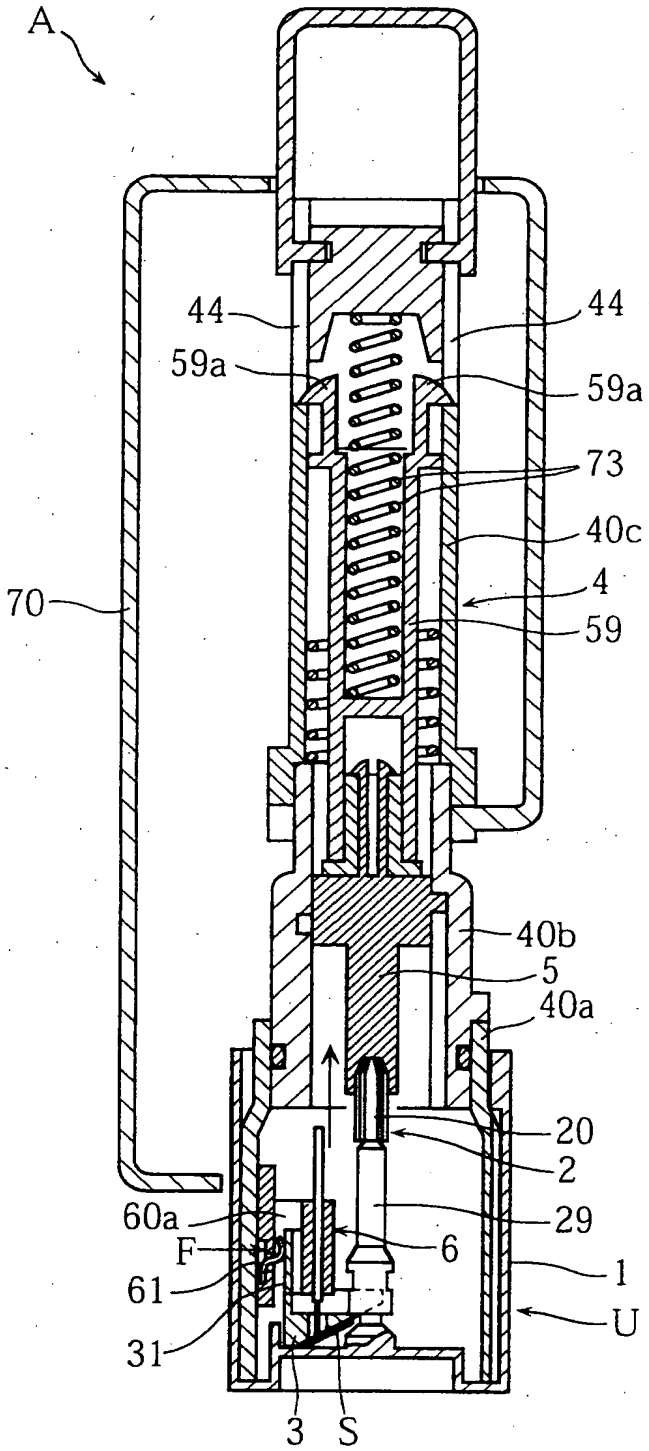
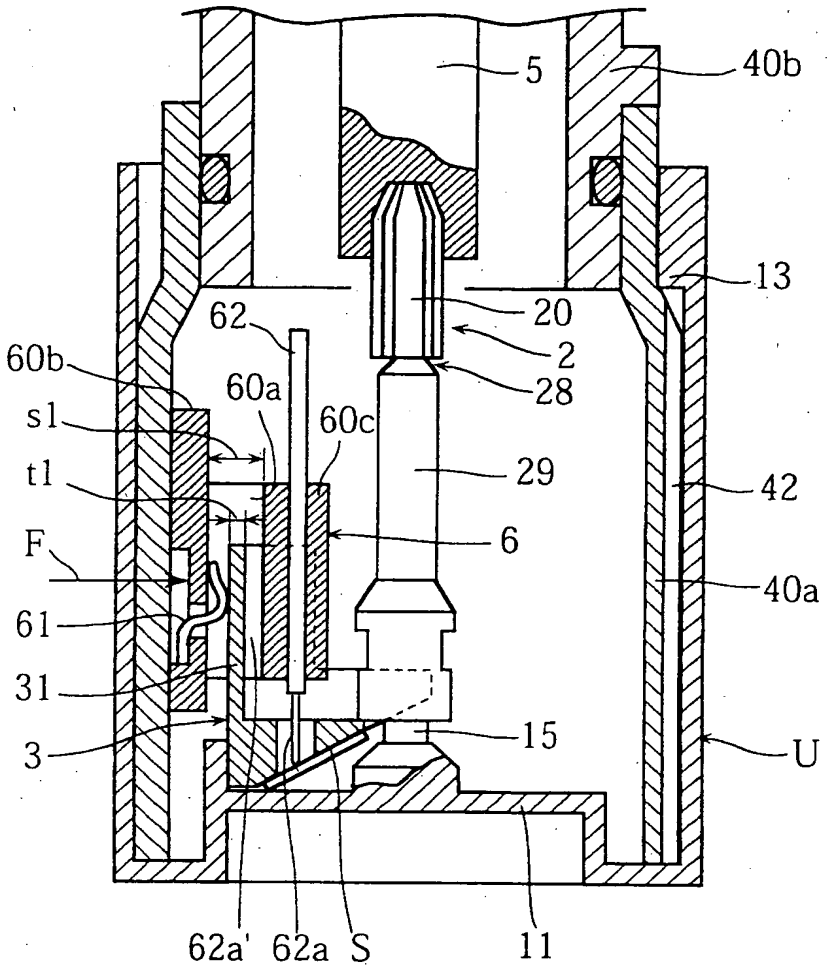
62a
1
3
15
32a
S
U

【Fig. 12】



【Fig. 13】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2
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s1
60c
t1
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42
F
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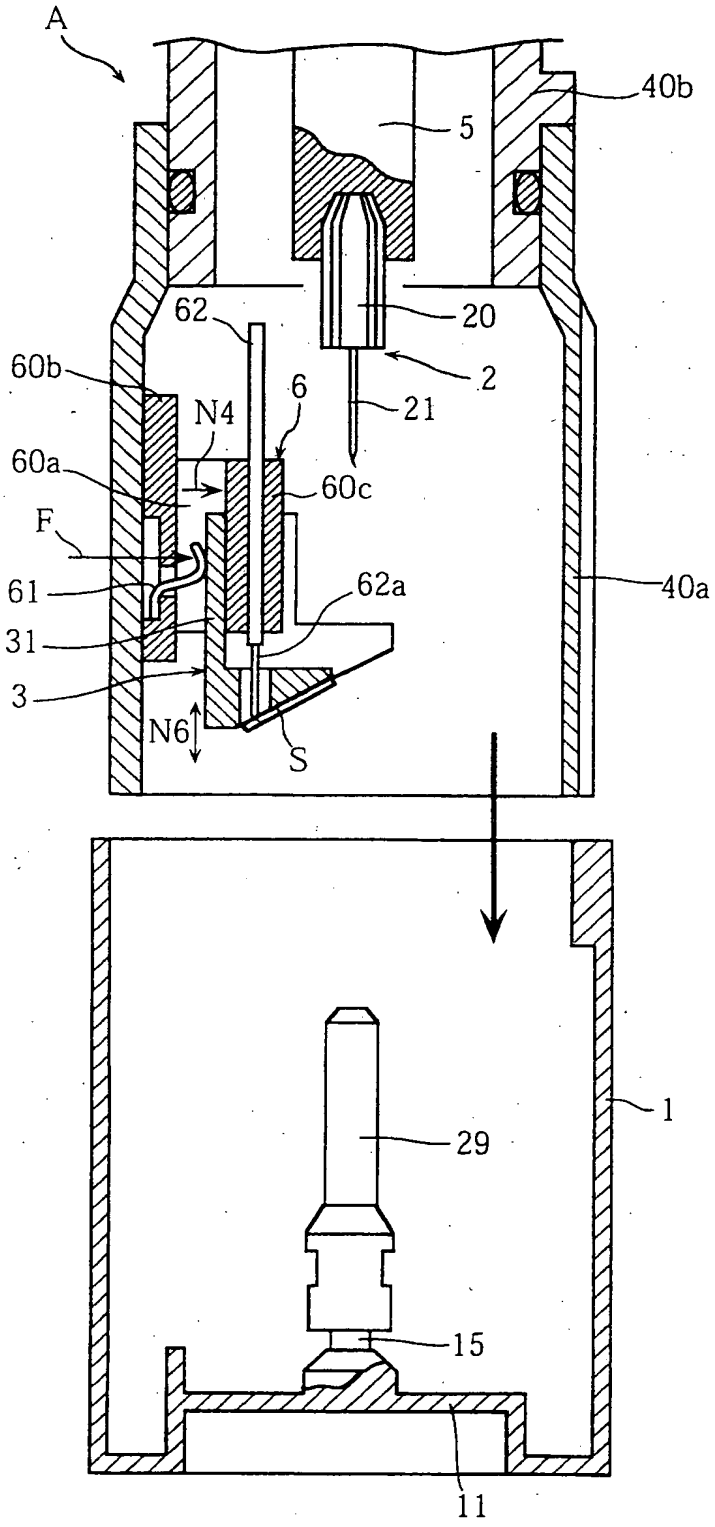
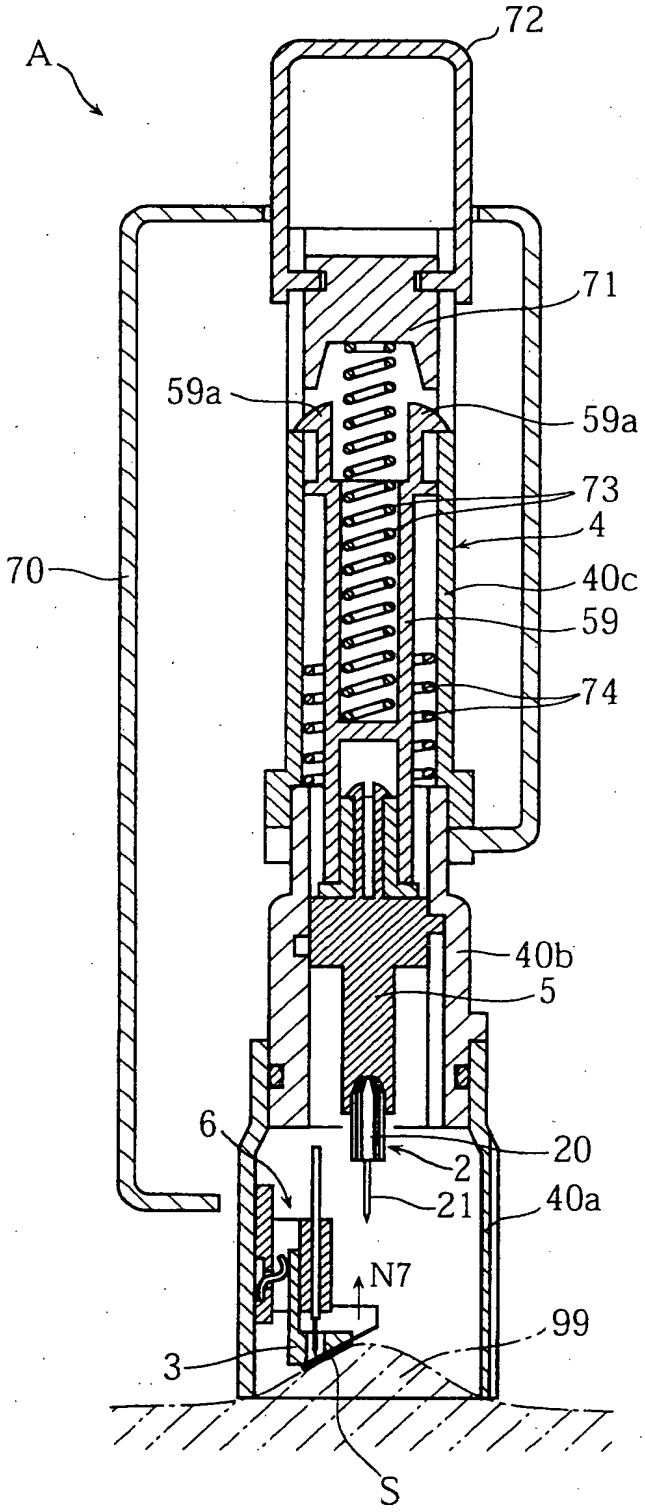
61
31
15
U
3
62a'
62a
S
11

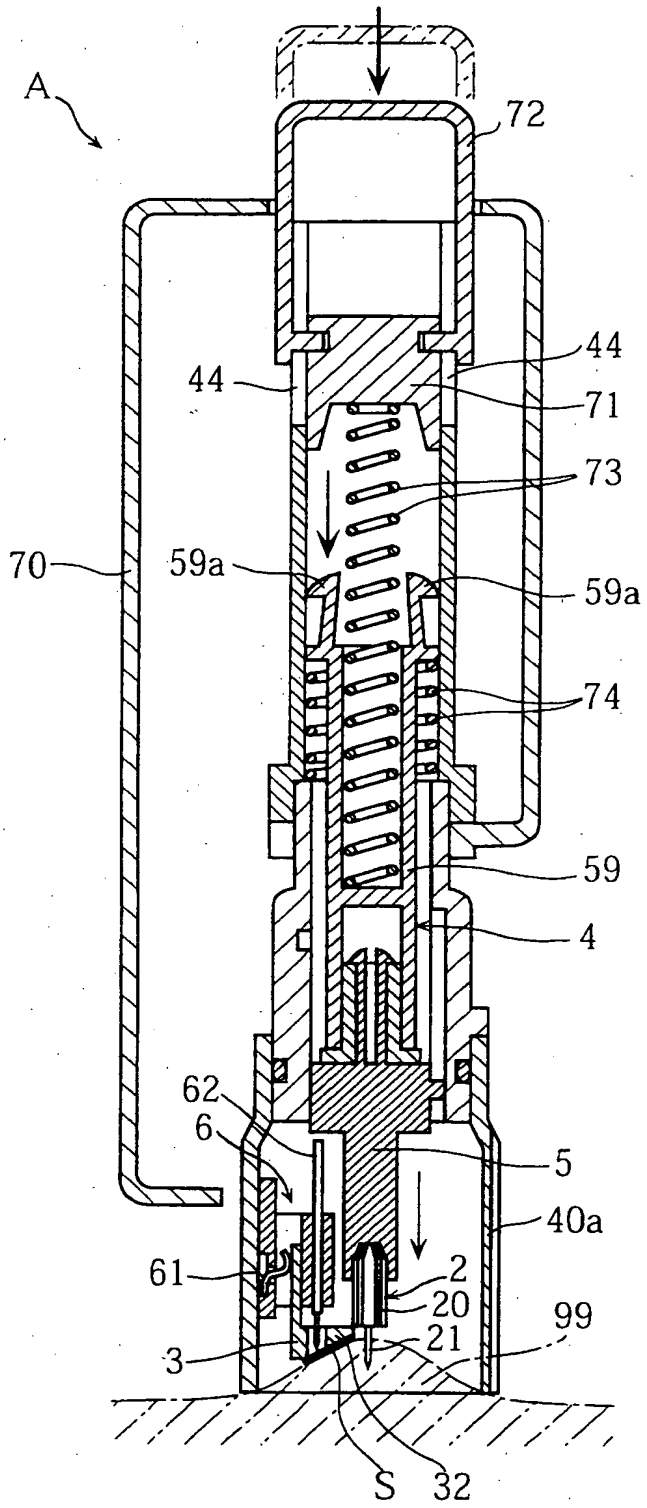
【Fig. 14】



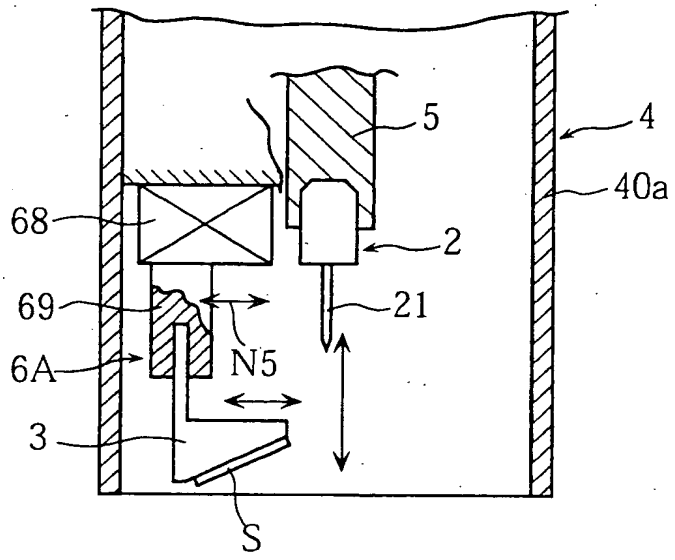
【Fig. 15】



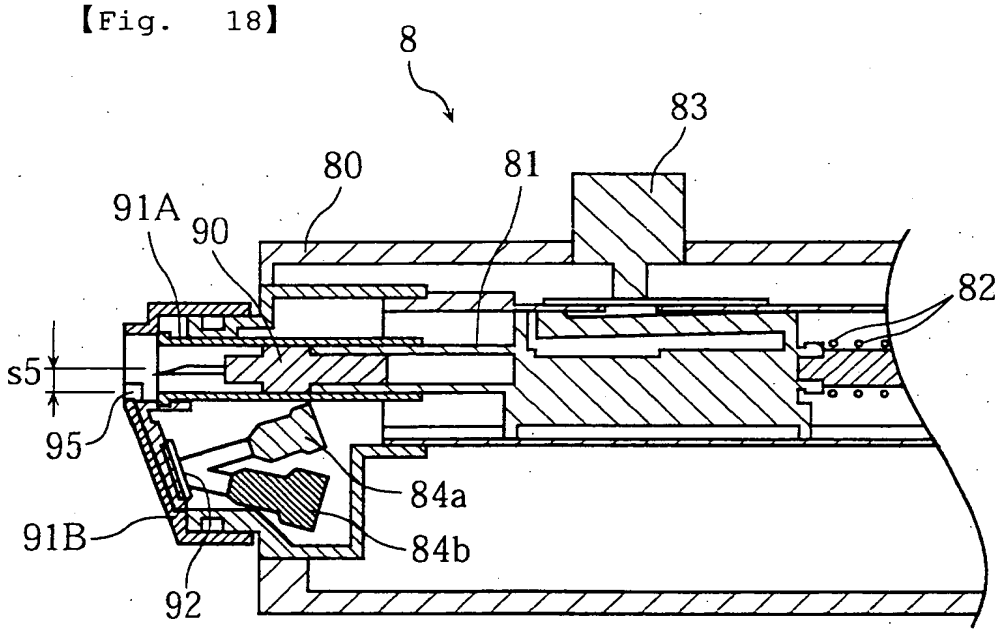
【Fig. 16】



【Fig. 17】



【Fig. 18】



【Fig. 19】